

U.S. DISTRICT COURT
DISTRICT OF VERMONT
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FOR THE
DISTRICT OF VERMONT

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DEPUTY CLERKUCB, INC., UCB PHARMA GMBH,
and LTS LOHMANN THERAPIE-
SYSTEME AG,

Plaintiffs,

v.

MYLAN TECHNOLOGIES, INC.,

Defendant.

Case No. 2:19-cv-128

OPINION AND ORDER
RE: CLAIM CONSTRUCTION
(Docs. 51, 57, 58, 75, & 76)

On July 16, 2019, Plaintiffs UCB, Inc. (“Plaintiff UCB”), UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively, “Plaintiffs”) filed a Complaint alleging that Defendant Mylan Technologies, Inc. (“Defendant”) infringed two patents, United States patent No. 10,130,589 B2 (the “‘589 patent”) and United States patent No. 10,350,174 B2 (the “‘174 patent”) (collectively, the “patents-in-suit”), in Defendant’s Abbreviated New Drug Application No. 209982 (the “ANDA”) seeking to market a generic version of Plaintiffs’ Neupro®. Plaintiffs seek a declaratory judgment that further pursuit of the ANDA would constitute infringement of both patents-in-suit and seek an injunction preventing Defendant from further infringement, as well as an award of damages, attorneys’ fees, and costs.

Defendant has filed an Answer, Defenses, and Counterclaims seeking, among other things, a declaration that the claims of the ‘589 and ‘174 patents are invalid and a declaration that the manufacture, use, sale, offer for sale, or importation of the drug product which is the subject of the ANDA has not infringed, would not induce infringement, and would not contributorily infringe any valid or enforceable claim of the patents-in-suit.

On March 10, 2020, the court held a claims construction hearing at which the parties presented oral argument regarding two contested terms in the patents-in-suit.

Plaintiffs are represented by Anthony D. Raucci, Esq., Catherine H. McCord, Esq., Derek J. Fahnestock, Esq., Jack B. Blumenfeld, Esq., James S. Trainor, Jr., Esq., Kendall A. Hoechst, Esq., Kevin X. McGann, Esq., Peter C. Richardson, Esq., Ritchie E. Berger, Esq., Silvia M. Medina, Esq., and Traci J. Medford-Rosow, Esq. Defendant is represented by Alissa M. Pacchioli, Esq., Deepro R. Mukerjee, Esq., Jittendra Malik, Esq., Lance A. Soderstrom, Esq., Michael F. Hanley, Esq., and Paul J. Perkins, Esq.

I. Factual Background.

Plaintiff UCB's anti-Parkinson's FDA-approved drug, Neupro®, is a transdermal therapeutic system ("TTS" or "transdermal patch") that continuously releases the active ingredient, rotigotine, in its free base form. The physiological "mechanism of action" of rotigotine is that it acts as a synthetic dopamine agonist that interacts with dopamine receptors in the human central nervous system, including the brain, to treat symptoms of Parkinson's disease and restless leg syndrome. Neupro® is intended to release rotigotine in a sustained, continuous drug delivery system.

Shortly after Neupro® was introduced to the United States market, it was involuntarily removed when it was determined that crystallization of the rotigotine in the transdermal patch was inhibiting the drug's ability to permeate the skin and enter the patient's circulatory system and when it was further determined that the original formulation of Neupro® was no longer stable at room temperature for the shelf life of the product.

The inventions described and claimed in the '174 and '589 patents-in-suit are both entitled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine" and were intended to stabilize solid dispersions of rotigotine in the transdermal patch to ensure against the precipitation/appearance of rotigotine crystals.

The '174 and '589 patents-in-suit reflect the same inventorship and are both continuations of the same parent patent, United States patent No. 9,925,150, and have the same specifications.

Claim 1 of the '589 patent states:

1. A method for stabilizing rotigotine, the method comprising providing a solid dispersion comprising polyvinylpyrrolidone and a non-crystalline form of rotigotine free base, wherein the weight ratio of rotigotine free base to polyvinylpyrrolidone is in a range from about 9:4 to about 9:6.

(Doc. 1-1 at 15.)

Claim 1 of the '174 patent states:

1. A stable solid dispersion comprising a silicone dispersing agent which is a two-part mixture of solution-based silicones and a dispersed phase, said dispersed phase comprising rotigotine free base and polyvinylpyrrolidone, wherein a weight ratio of rotigotine free base to polyvinylpyrrolidone is about 9:4 to about 9:6.

(Doc. 1-2 at 15.)

Pending before the court is the proper construction of “[a] method for stabilizing rotigotine” in claim 1 of the '589 patent and “[a] stable solid dispersion” in claim 1 of the '174 patent.

II. The Delaware Decision.

Plaintiffs are pursuing parallel litigation against nonparty Actavis Laboratories UT, Inc. in the District of Delaware for alleged infringement of the '589 patent. On February 7, 2020, the United States District Court for the District of Delaware issued an opinion (the “Delaware Decision”) holding that the phrase “[a] method for stabilizing rotigotine” in the preamble of claim 1 of the '589 patent is nonlimiting and did not require construction. *UCB, Inc. v. Actavis Labs. UT, Inc.*, 2020 WL 599446, at *2 (D. Del. Feb. 7, 2020) (internal quotation marks omitted). The court reasoned that “the claim body defines a structurally complete invention and the claim uses the preamble only to state the purpose or intended use of the invention.” *Id.*

For the purposes of this lawsuit, the parties ask the court to adopt the conclusion of the Delaware Decision that the preamble is nonlimiting with respect to claim 1 of the '589 patent subject to Plaintiffs' reservation of the right to appeal either the Delaware Decision or an opinion of this court adopting the Delaware Decision.

III. Conclusions of Law and Analysis.

A. Standard of Review.

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Claims "are generally given their ordinary and customary meaning"; that is, "the meaning that the term would have to a person of ordinary skill in the art [("POSA")] in question at the time of the invention[.]" *Id.* at 1312-13 (internal quotation marks omitted). This meaning is to be discerned "in the context of the entire patent, including the specification[.]" *id.* at 1313, and with reference to the prosecution history if necessary.

It is hornbook law that "the claims are 'of primary importance[] in the effort to ascertain precisely what it is that is patented[.]'" *id.* at 1312 (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876)), and for that reason claim construction "begins and ends in all cases with the actual words of the claim." *Google LLC v. Network-1 Techs., Inc.*, 726 F. App'x 779, 785 (Fed. Cir. 2018) (internal quotation marks omitted). Nonetheless, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed Cir. 1996)).

B. The Delaware Decision's Ruling that the '589 Patent's Preamble is Nonlimiting.

The Delaware court found that "a method for stabilizing rotigotine" as it appears in claim 1 of the '589 patent is a nonlimiting preamble because it merely "state[s] the purpose or intended use of the invention[]" and "requires no construction." *UCB, Inc.*, 2020 WL 599446, at *2.

[A] preamble is a claim limitation if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. On the other hand, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.

Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303, 1309-10 (Fed. Cir. 2004) (citation and internal quotation marks omitted).

“Whether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history[,]” but “as a general rule[,] preamble language is not treated as limiting.” *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019) (alteration and internal quotation marks omitted).

In this case, with the parties’ consent, the court hereby ADOPTS the Delaware Decision’s well-reasoned determination that “the preamble of claim 1 [of the ‘589 patent,] ‘a method for stabilizing rotigotine,’ is not limiting” as well as the Delaware court’s further conclusion that “a method for stabilizing rotigotine” requires no construction. *UCB, Inc.*, 2020 WL 599446, at *2.

C. Construction of “Stable Solid Dispersion” (Claim 1 of the ‘174 Patent).

The parties contest the meaning of the term “stable solid dispersion” as it appears in claim 1 of the ‘174 patent:

A stable solid dispersion comprising a silicone dispersing agent which is a two-part mixture of solution-based silicones and a dispersed phase, said dispersed phase comprising rotigotine free base and polyvinylpyrrolidone, wherein a weight ratio of rotigotine free base to polyvinylpyrrolidone is about 9:4 to about 9:6.

(Doc. 1-2 at 15) (emphasis supplied).

The parties agree that a POSA would understand “solid dispersion” to mean rotigotine that is “dispersed” throughout the transdermal patch as opposed to aggregated in crystallized particles as this was the very problem the patents-at-issue sought to address (the crystallization of rotigotine in a transdermal patch). The parties, however, contest the proper construction of the term “stable.”

Plaintiffs assert that the proper construction of “stable solid dispersion” should be: “[A] solid dispersion capable of maintaining the non-crystalline rotigotine in non-crystalline form for at least 2 years at room temperature or temperatures not exceeding 25° C.” (Doc. 75 at 5-6) (footnote and internal quotation marks omitted) (citing Doc 1-2 at 10, col. 5:60-66). They point out that the time and temperature conditions are used in conjunction with a clear intent to set forth a definition in the specification through the use of the words: “The term ‘stabilization’ as used herein means” (Doc. 1-2 at 10.) They further contend that the ability of the suspension to maintain stability consistent with the specific time and temperature parameters of 2 years and 25° C is “the very essence of the inventors’ solution[.]” (Doc. 75 at 5.)

Defendant counters that the term “stable solid dispersion” should be given its plain and ordinary meaning and does not require claim construction. In the alternative, Defendant contends that if construction is necessary, “stable solid dispersion” should be construed to mean “[a] solid dispersion which exhibits inhibited crystallization.” (Doc. 51 at 6.) Defendant points out that “stable” has the same meaning as “stabilization” and “stabilizing” and cites the ‘589 patent for the proposition that “stabilization” means “that the non-crystalline form of rotigotine in a solid dispersion is maintained due to preventing rotigotine from crystallization over a certain period of time under defined conditions.” (Doc. 1-1 at 10.)¹ The ‘174 patent is a continuation of the ‘589 application which does not include the two years and 25° C limitations. As Defendant points out,

¹ Defendant notes that in the Delaware litigation, Plaintiffs appeared to agree that “[a] method for stabilizing rotigotine” was an express limitation that did not require construction and carried its plain and ordinary meaning, and that Plaintiffs’ alternatively proposed construction was: “A method for inhibiting rotigotine crystallization[.]” (Doc. 51 at 3.) After filing this lawsuit in Vermont, Plaintiffs notified the Delaware court that, in contradistinction to the position they took in Delaware, in this case, their proposed claim construction incorporates additional temperature and time requirements, specifically “at least 2 years at room temperature or temperatures not exceeding 25° C[.]” *Id.* In non-binding *dicta*, the Delaware court observed that “Plaintiffs’ Vermont construction incorporates an embodiment disclosed in the specification” and that “claims are not typically limited to the embodiments disclosed in the specification, even when just one such embodiment (or type of embodiment) is disclosed.” *UCB, Inc. v. Actavis Labs. UT, Inc.*, 2020 WL 599446, at *2 n.4 (D. Del. Feb. 7, 2020) (internal quotation marks omitted).

“unless otherwise compelled, . . . the same claim term in the same patent or related patents carries the same construed meaning.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003).

Defendant further observes that the two-year and 25° C time and temperature limitations are only one of several embodiments set forth in the entirety of the specification for the ‘174 patent and that nothing in the prosecution history for the ‘174 patent suggests a special definition for “stable solid dispersion.”

“There is a heavy presumption that claim terms are to be given their ordinary and customary meaning.” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1358 (Fed. Cir. 2017) (internal quotation marks omitted). However, “‘the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning’ of terms in a claim.” *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 (Fed. Cir. 2017) (quoting *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003)). “The written description and other parts of the specification[] . . . may [therefore] shed contextual light on the plain and ordinary meaning[.]” *Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013).

“[A] claim term is only given a special definition different from the term’s plain and ordinary meaning if the ‘patentee . . . clearly set[s] forth a definition of the disputed claim term other than its plain and ordinary meaning.’” *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1375 (Fed. Cir. 2015) (omission and second alteration in original). For the patentee’s definition to apply, the patentee must “clearly express an intent to redefine the term.” *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotation marks omitted).

Plaintiffs’ proposed claim construction seeks to “cherry-pick” by importing some, but not all, limitations from the specification into the construction of “stable solid dispersion,” ignoring the following bolded portions of the specification:

The term “stabilization” as used herein means that the non-crystalline form of rotigotine in a solid dispersion is maintained due to preventing rotigotine from crystallization over a certain period of time under defined conditions.

In particular, a stabilization of at least 2 years under storage at room temperature or temperatures not exceeding 25° C[] is intended. **This means that degree of rotigotine crystallization in the solid dispersion should not exceed 10%, more preferably should not exceed 5%[,] and most preferably should not exceed 2%** (all percentages used herein are by weight, unless provided otherwise), based on the initial amount of rotigotine in the solid dispersion after 24 months **storage in a sealed container at room temperature.**

(Doc. 1-1 at 10) (emphasis supplied).

While the term “stabilization” in the specification in the ‘174 patent “is set off by quotation marks—often a strong indication that what follows is a definition[,]” *Sinorgchem Co., Shandong v. Int’l Trade Comm’n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007), there is no clear intent to redefine “stabilization” so that it differs from the meaning set forth in the ‘589 patent. Instead, the additional limitations Plaintiffs seek to import are contained in a separate sentence prefaced by “[i]n particular,” which, in turn, makes clear that two years and 25° C are not fixed parameters, but only minimum and maximum limits on the temperature and time conditions intended. (Doc. 1-1 at 10.) In other words, a spectrum of room temperatures is intended provided they do not exceed 25° C just as varying time limitations are intended provided they are at least two years. In this respect, the additional limitations are not definitional in nature but merely describe conditions in which “stabilization” can be expected to occur. Other conditions in which “stabilization” may occur are set forth elsewhere in the specification. Plaintiffs offer no persuasive explanation as to why only some of the limitations noted in the specification should be imported into the construction of “stable solid dispersion,” while others are omitted.

“[L]imitations from the specification may [not] be read into the claims[,]” *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998), and “although the specification often describes very specific embodiments of the invention, [courts] have repeatedly warned against confining the claims to those embodiments.” *Phillips*, 415 F.3d at 1323.


In this case, the court finds that a POSA would understand that the plain and ordinary meaning of “stable solid dispersion” is “a solid dispersion which exhibits inhibited crystallization” because “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Not only is this construction supported by the language of the claim itself, it is consistent with the entirety of the ‘174 patent and its prosecution history. Defendant thus prevails in its proposed alternative claim construction.

CONCLUSION

For the foregoing reasons, the court hereby ADOPTS the Delaware Decision’s determination that the preamble of claim 1 of the ‘589 patent, “a method for stabilizing rotigotine,” is nonlimiting and requires no construction. The court HEREBY CONSTRUES “stable solid dispersion” in claim 1 of the ‘174 patent in accordance with its plain and ordinary meaning as “a solid dispersion which exhibits inhibited crystallization.”

SO ORDERED.

Dated at Burlington, in the District of Vermont, this 8th day of May, 2020.


Christina Reiss, District Judge
United States District Court